K072216

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510(k) Summary

Submitter:	Kapp Surgical Instrument, Inc 4919 Warrensville Center Road Cleveland, OH 44128FDA
Contact person:	Albert Santilli President Kapp Surgical Instrument, Inc 4919 Warrensville Center Road Cleveland, OH 44128 Phone: (216) 587-4400 Fax: (216) 587-0411 E-mail: ans@kappsurgical.com
Date summary prepared:	August 8, 2007
Device trade name:	Bari-Ring Endoscopic Marker
Device common name:	Marker Ring
Device classification name:	Marker, Radiographic, Implantible NEU 21 CFR Part 878.4300
Legally marketed devices to which the device is substantially equivalent:	KAPP Bari-Ring Endoscopic Marker, Model KS-BR-2005, K050384 MRI Devices Corporation ClipLoc Soft Tissue Marker, K033447
Description of the device:	The KAPP Bari-Ring Endoscopic Marker consists of a nickel titanium stainless steel ring deployed during surgery. It is supplied non-sterile for single long term (30 day) use to mark the spot expected to require further surgery within 30 days. The ring is homogenously constructed of a ring of nickel titanium conforming to ASTM F 2063-05.
Intended use of the device:	The KAPP Bari-Ring Endoscopic Marker is intended to be used for radiographically marking the current site of surgery for future surgical procedures.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).

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Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: • Corrosion resistance • Hardness • Tensile
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Albert N. Santilli, Ph.D.
President
Kapp Surgical Instrument, Inc.
4919 Warrrensville Center Rd.
CLEVELAND OH 44128

Re: K072216
Trade/Device Name: KAPP Bari-Ring Endoscopic Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: October 9, 2007
Received: October 11, 2007

Dear Dr. Santilli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K072216

Device Name: KAPP Bari-Ring Endoscopic Marker

Indications for Use: The KAPP Bari-Ring Endoscopic Marker is intended to be used to radiographically (limited to x-ray) mark the site of gastropexy performed during bariatric or other surgical procedures, especially in those procedures where the stomach is not accessible by other diagnostic means (contrast or endoscopy).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072216